DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 2, 2015

Iridex Corporation
c/o Ms. Kathy Maynor
Regulatory Consultant
26 Rebecca St.
Homosassa, FL 34446

Re: K143154
Trade/Device Name: Iridex Cyclo G6 (with delivery devices)
Regulation Number: 21 CFR 878.4810
Regulation Name: Power Laser Surgical Instruments
Regulatory Class: Class II
Product Code: GEX
Dated: December 4, 2014
Received: December 5, 2014

Dear Ms. Maynor:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Deborah L. Falls -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See *PRA Statement on last page.*

51O(k) Number *(if known)*

K143154"

Device Name

Family of IR.IDEX® IQ Laser Systems (IQ 532, IQ 577, IQ 630-670, IQ 81O[IRIDEX Cyclo G6 Laser System])

Indications for Use *(Describe)*

The Family of IR.IDEX® IQ Laser Systems (IQ 532 [532nm], IQ 577 [577nm], IQ 630-670 [630nm-670nm], IQ 810 [810nm] [IRIDEX Cyclo G6 Laser System]) and the hand pieces, delivery devices & accessories that are used with them to deliver laser energy in either CW-pulse, MicroPulseTM or LongPulse TM mode. Intended for soft and fibrous tissue, including osseous tissue incision, excision, coagulation, vaporization, ablation and vessel hemostasis in the medical specialties of, dermatology, ear, nose and throat (ENT)/ otolaryngology, and ophthalmology as follows:

810nm (IRIDEX Cyclo G6 Laser System)

Ophthalmology:

The IRIDEX® Cyclo G6 Laser System and Probe Delivery Devices (G-Probe & MicroPulse P3) are used to deliver laser energy in either CW-Pulse (CW) or MicroPulse™ (μP) treatment mode and indicated for the treatment of Glaucoma:

	Condition (Indicated for)	Treatment (Intended Use)	CW/μP
MicroPulse P3 Device	For the treatment of Glaucoma including: • Primary Open-Angle • Closed-Angle • Refractory	Transscleral cyclophotocoagulation (TSCPC) of the ciliary processes	μP
G-Probe	For the treatment of Glaucoma including: • Primary Open-Angle • Closed-Angle • Refractory	Transscleral cyclophotocoagulation (TSCPC) of the ciliary processes	CW

Type of Use *(Select one or both,* as *applicable)*

Prescription Use (Part 21 CFR 801 Subpart D) O Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Section 8 – Special 510(k) Summary

I. General Information

Submitter:

Iridex Corporation

Contact Person:

Kathy Maynor

kmaynor77@gmail.com

352-586-3113 (cell)

Summary Preparation Date: October 31, 2014

II. Names

Device Name(s): Cyclo G6

Primary Classification Name(s): Electrosurgical cutting and coagulation device and accessories

III. Predicate Devices

- K071687 – Family of Iridex IQ Laser Systems (IQ 532, IQ 577, IQ 630-670, IQ 810)

IV. Product Description

The Iridex Cyclo G6 is comprised of the following main components:

- Main console containing the major electrical components, including:
  - Control Panel including control knobs (power, interval, duration or software assigned function), treat/standby button, and display;
  - Two delivery device fiber-optic connector ports (only one active at a time);
  - LIO illumination connection;
  - Smart key port for detecting/operating safety filters and/or accessory identification;
  - Emergency stop switch;
  - Key switch;
  - Connector ports for the footswitch, remote control, and power cord;
  - A treatment Footswitch (either wired, wireless, or wireless with PowerAdjust);
  - A Wired Remote Control that duplicates the control panel;
  - Delivery Accessories including G-Probeand MicroPulse P3 probe Handpieces, Microscope Adapters, and Laser Indirect Ophthalmoscopes (these are not used with the Cyclo G6 but are available for use with the other members of the laser family).
  - Optional Cart/Stand

V. Indications for Use

lndications for Use (same as K071687):

The Family of IRIDEX® IQ Laser Systems (IQ 532 [532nm], IQ 577 [577nm], IQ 630-670 [630nm-670nm], IQ 810 [810nm]) and the hand pieces, delivery devices & accessories that are used with them to deliver laser energy in either CW-pulse, MicroPulse™ or LongPulse ™ mode. Intended for soft and fibrous tissue, including osseous tissue incision, excision, coagulation, vaporization, ablation and vessel hemostasis in the medical specialties of, dermatology, ear, nose and throat (ENT)/ otolaryngology, and ophthalmology as follows:

532 nm

Dermatology

- Pigmented Skin Lesions
- Vascular Lesions

Ear, Nose, and Throat (ENT)/ Otolaryngology

Otosclerotic Hearing loss and/or diseases of the inner ear:

- Stapedectomy
- Stapedotomy
- Myringotomies
- Lysis of Adhesions
- Control of Bleeding

- Removal of Acoustic Neuromas
- Soft tissue Adhesion in Micro/Macro Otologic Procedures

Ophthalmology

Indicated for retinal photocoagulation, laser trabeculoplasty, iridotomy, iridoplasty including:

- Retinal photocoagulation (RPC) for the treatment of
    - Diabetic retinopathy, including:
        - Nonproliferative retinopathy
        - Macular edema
        - Proliferative retinopathy
    - Retinal tears and detachments
    - Lattice degeneration
    - Age-related macular degeneration (AMD)
    - Retinopathy of prematurity
    - Sub-retinal (choroidal) neovascularization
    - Central and branch retinal vein occlusion
- Laser trabeculoplasty, iridotomy, iridoplasty for the treatment of glaucoma, including
    - Primary open angle/Closed angle

577nm

Dermatology:

- Treatment of Vascular and pigmented lesions

Ophthalmology:

Indicated for use in photocoagulation of both anterior and posterior segments including:

- Retinal photocoagulation, panretinal photocoagulation and intravitreal endophotocoagulation of vascular and structural abnormalities of the retina and choroid including :
    - proliferative and nonproliferative diabetic retinopathy;
    - choroidal neovascularization;
    - branch retinal vein occlusion;
    - age-related macular degeneration
    - retinal tears and detachments
    - retinopathy of prematurity
- Iridotomy, iridectomy and trabeculoplasty in angle closure glaucoma and open angle glaucoma

810nm

Ophthalmoloqgy:

Indicated for retinal photocoagulation, laser trabeculoplasty, transscleral cyclophotocoagulation, transscleral retinal photocoagulation, iridotomy, including the following examples:

- Retinal photocoagulation for the treatment of:
  - Diabetic retinopathy, including:
    - Nonproliferative retinopathy
    - Macular edema
    - Proliferative retinopathy
  - Retinal Tears, Detachments and Holes
  - Lattice degeneration
  - Age-related macular degeneration (AMD) with choroidal neovascularization (CNV)
  - Retinopathy of prematurity
  - Sub-retinal (choroidal) neovascularization
  - Central and Branch Retinal Vein Occlusion
- Laser trabeculoplasty, Iidotomy, Transscleral Cyclophotocoagulation (TSCPC) for the treatment of glaucoma, including:
  - Primary open angle
  - Closed angle
  - Refractory Glaucoma (recalcitrant/uncontrolled)

No clinical data was needed for these indications. They are identical to those on K071687.

VI. Summary of Technological Characteristics

The technological characteristics of the Iridex Cyclo G6 laser are substantially equivalent to those of the predicate device.

Characteristic	**Iridex Cyclo G6**	**K071687** Iridex Family of IQ Lasers
Product Code Regulation	General & Plastic Surgery • GEX, 21 CFR 878.4810	General & Plastic Surgery • GEX, 21 CFR 878.4810
Intended Use	Intended for use in dermatology, ear, nose and throat (ENT)/ otolaryngology, and ophthalmology	Intended for use in dermatology, ear, nose and throat (ENT)/ otolaryngology, and ophthalmology
Indications for Use	Exactly the same as K071687	See K071687
Wavelength	810nm	532nm, 577nm, 630-670nm, 810nm

Characteristic	Iridex Cyclo G6	K071687 Iridex Family of IQ Lasers
Aiming beam	630nm-650nm	630nm-650nm
Power Watts	≤ 5W	≤ 5W
Pulse Duration (usec)	10µsec-60min	10µsec-60min
Output Mode	CW (CW-Pulse, MicroPulse, Long Pulse)	CW (CW-Pulse, MicroPulse, Long Pulse)
Repetition rate	≤ 1kHz	≤ 1kHz
Laser media	Diode, Diode-pumped, frequency doubled, solid state	Diode, Diode-pumped, frequency doubled, solid state
User interface	Manual & Remote Controls	Manual & Remote Controls
Laser activation	footswitch	footswitch
Delivery devices, how supplied	Delivery Devices provided Sterile packaged & non-sterile	Delivery Devices provided Sterile packaged & non-sterile
Electrical requirements	90-130 VAC, 50/60 Hz 200-240 VAC, 50/60 Hz	90-130 VAC, 50/60 Hz 200-240 VAC, 50/60 Hz

VII. Safety and Effectiveness Information

The review of the indications for use and technical characteristics provided demonstrates that the Iridex Cyclo G6 Laser is substantially equivalent to the predicate device and is safe and effective for use for the various indications for use stated.

The software changes that are the subject of this 510(k) were verified and validated in accordance with the Iridex design control procedures.

VIII. Conclusion

The Iridex G6 Laser was found to be substantially equivalent to the predicate device.

The Iridex G6 Laser shares identical indications for use, similar design features, and functional features with, and thus are substantially equivalent to, the predicate device.